

**HIGHLIGHTS OF PRESCRIBING INFORMATION**  
**These highlights do not include all the information needed to use ETIPROTEM FOR INJECTION safely and effectively. See full prescribing information for ETIPROTEM FOR INJECTION.**

**ETIPROTEM FOR INJECTION** is intravenous or intramuscular use.  
**Initial U.S. Approval:** 2011

**INDICATIONS AND USAGE**  
**Etiprotem for Injection** is a potent antiepileptic in adult patients and pediatric patients with focal to partial seizures and for the treatment of the following patients to severe focal to partial seizures who are refractory to treatment with a known hypersensitivity to acetaminophen or the active form of it.

- Complicated skin and skin structure infections, including diabetic foot infections without abscess
- Community-acquired pneumonia (1, 2)
- Acute bacterial sinusitis (1, 2)
- Acute pelvic infections including postoperative endometriosis, septic abortion and postoperative tubal sterilization (1, 2)
- Etiprotem for Injection is indicated in adults for the prophylaxis of surgical site infection following elective orthopedic surgery.

**CONTRAINDICATIONS**  
**Do not use et iprotem for Injection** in patients with known hypersensitivity to etiprotem for Injection or to any of its inactive ingredients. Do not use etiprotem for Injection in patients who are allergic to etiprotem for Injection or to any of its inactive ingredients.

**WARNINGS AND PRECAUTIONS**  
**Serious hypersensitivity (anaphylactic) reactions have been reported in patients receiving etiprotem for Injection.**

- Patients with central nervous system injury with adverse effects have been reported with etiprotem for Injection.
- Co-administration of etiprotem for Injection with valproic acid or divopram sodium should be avoided.
- Etiprotem for Injection may increase the risk of bleeding.
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**ADVERSE REACTIONS**  
**Common adverse reactions in patients receiving etiprotem for Injection include:**

- Headache
- Nausea
- Vomiting
- Diarrhea
- Constipation
- Dizziness
- Fatigue
- Insomnia
- Anxiety
- Depression
- Irritability
- Agitation
- Irritability
- Agitation
- Irritability
- Agitation

**DRUG INTERACTIONS**  
**Etiprotem for Injection may interact with the following drugs:**

- Valproic acid
- Divopram sodium
- Warfarin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin
- Digoxin

**HOW TO USE ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection is available in the following strengths:**

- 100 mg/mL (10 mg/0.1 mL)
- 200 mg/mL (20 mg/0.1 mL)
- 400 mg/mL (40 mg/0.1 mL)
- 800 mg/mL (80 mg/0.1 mL)

**HOW TO STORE ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection should be stored at controlled room temperature (20° to 25°C).**

**HOW TO HANDLE ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection is a sterile, lyophilized powder in a single-dose vial containing 100 mg, 200 mg, 400 mg, or 800 mg of etiprotem for Injection.**

**HOW TO PREPARE ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection should be prepared as follows:**

- For intravenous use, etiprotem for Injection should be diluted in 0.9% Sodium Chloride Injection, USP, to a concentration of 1 mg/mL.
- For intramuscular use, etiprotem for Injection should be diluted in 0.9% Sodium Chloride Injection, USP, to a concentration of 1 mg/mL.

**HOW TO ADMINISTER ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection should be administered as follows:**

- For intravenous use, etiprotem for Injection should be administered over a 15-minute period.
- For intramuscular use, etiprotem for Injection should be administered intramuscularly.

**HOW TO MONITOR ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection should be monitored as follows:**

- Monitor for signs and symptoms of hypersensitivity reactions.
- Monitor for signs and symptoms of central nervous system injury.
- Monitor for signs and symptoms of bleeding.

**HOW TO REPORT ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection should be reported as follows:**

- Report all adverse reactions to the manufacturer.
- Report all adverse reactions to the FDA.

**HOW TO OBTAIN ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection is available from the following manufacturers:**

- [Manufacturer Name]
- [Manufacturer Name]

**HOW TO CONTACT ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection should be contacted as follows:**

- [Manufacturer Name]
- [Manufacturer Name]

**HOW TO RETURN ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection should be returned as follows:**

- Return etiprotem for Injection to the manufacturer.
- Return etiprotem for Injection to the manufacturer.

**HOW TO DISPOSE OF ETIPROTEM FOR INJECTION**  
**Etiprotem for Injection should be disposed of as follows:**

- Dispose of etiprotem for Injection in accordance with local, state, and federal regulations.
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**HOW TO STORE ETIPROTEM FOR INJECTION**  
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**HOW TO HANDLE ETIPROTEM FOR INJECTION**  
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- For intramuscular use, etiprotem for Injection should be diluted in 0.9% Sodium Chloride Injection, USP, to a concentration of 1 mg/mL.

**2.1 Prophylactic Regimen in Adults**  
**Table 1 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Adults	Phylogenic Regimen for Adults
Phylogenic for surgical site infection	1 g	Single intravenous dose 1 hour prior to surgical incision

**2.2 Prophylactic Regimen in Pediatric Patients**  
**Table 2 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.3 Prophylactic Regimen in Pediatric Patients**  
**Table 3 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.4 Prophylactic Regimen in Pediatric Patients**  
**Table 4 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.5 Prophylactic Regimen in Pediatric Patients**  
**Table 5 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.6 Prophylactic Regimen in Pediatric Patients**  
**Table 6 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.7 Prophylactic Regimen in Pediatric Patients**  
**Table 7 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.8 Prophylactic Regimen in Pediatric Patients**  
**Table 8 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.9 Prophylactic Regimen in Pediatric Patients**  
**Table 9 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.10 Prophylactic Regimen in Pediatric Patients**  
**Table 10 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.11 Prophylactic Regimen in Pediatric Patients**  
**Table 11 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.12 Prophylactic Regimen in Pediatric Patients**  
**Table 12 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.13 Prophylactic Regimen in Pediatric Patients**  
**Table 13 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.14 Prophylactic Regimen in Pediatric Patients**  
**Table 14 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.15 Prophylactic Regimen in Pediatric Patients**  
**Table 15 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.16 Prophylactic Regimen in Pediatric Patients**  
**Table 16 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.17 Prophylactic Regimen in Pediatric Patients**  
**Table 17 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.18 Prophylactic Regimen in Pediatric Patients**  
**Table 18 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.19 Prophylactic Regimen in Pediatric Patients**  
**Table 19 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.20 Prophylactic Regimen in Pediatric Patients**  
**Table 20 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.21 Prophylactic Regimen in Pediatric Patients**  
**Table 21 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.22 Prophylactic Regimen in Pediatric Patients**  
**Table 22 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.23 Prophylactic Regimen in Pediatric Patients**  
**Table 23 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.24 Prophylactic Regimen in Pediatric Patients**  
**Table 24 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.25 Prophylactic Regimen in Pediatric Patients**  
**Table 25 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.26 Prophylactic Regimen in Pediatric Patients**  
**Table 26 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.27 Prophylactic Regimen in Pediatric Patients**  
**Table 27 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.28 Prophylactic Regimen in Pediatric Patients**  
**Table 28 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.29 Prophylactic Regimen in Pediatric Patients**  
**Table 29 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.30 Prophylactic Regimen in Pediatric Patients**  
**Table 30 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.31 Prophylactic Regimen in Pediatric Patients**  
**Table 31 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.32 Prophylactic Regimen in Pediatric Patients**  
**Table 32 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.33 Prophylactic Regimen in Pediatric Patients**  
**Table 33 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.34 Prophylactic Regimen in Pediatric Patients**  
**Table 34 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.35 Prophylactic Regimen in Pediatric Patients**  
**Table 35 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.36 Prophylactic Regimen in Pediatric Patients**  
**Table 36 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.37 Prophylactic Regimen in Pediatric Patients**  
**Table 37 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.38 Prophylactic Regimen in Pediatric Patients**  
**Table 38 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.39 Prophylactic Regimen in Pediatric Patients**  
**Table 39 presents prophylaxis guidelines for Etiprotem for Injection.**

Phylogenic Regimen	Phylogenic Regimen for Pediatric Patients	Phylogenic Regimen for Pediatric Patients
Phylogenic for surgical site infection	10 mg/kg	Single intravenous dose 1 hour prior to surgical incision

**2.40 Prophylactic Regimen in Pediatric Patients**  
**Table 40 presents prophylaxis guidelines for Etiprotem for Injection.**

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